Paper No. 28

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL REINHARD and MICHAEL SPALLEK

Appeal No. 1998-2183
Application No. 08/529,195

HEARD: APRIL 18, 2000

Before COHEN, FRANKFORT, and NASE, Administrative Patent Judges.

COHEN, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 13 through 32. These claims constitute all of the claims remaining in the application.

Appellants' invention pertains to a prefillable, low-particle, sterile, single use syringe for the injection of

preparations having a filling volume of less than 5 ml. An understanding of the invention can be derived from a reading of exemplary claims 13 and 24, a copy of which claims appears in the APPENDIX to the main brief (Paper No. 22).

As evidence, the examiner has applied the documents listed below:

Cloyd et al. (Cloyd)	3,330,004	Jul. 11, 1967
Onohara et al. (Onohara)	4,814,231	Mar. 21, 1989
Meyer	5,478,324	Dec. 26, 1995
Sudo (published European Patent Application)	0 556 034 A1	Aug. 18, 1993

The following rejections are before us for review.

Claims 13, 14, 16, 24, 26, 31, and 32 stand rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Sudo.

Claims 15 and 25 stand rejected under 35 U.S.C. § 103 as being unpatentable over Sudo in view of Cloyd.

Claims 17, 18, and 27 stand rejected under 35 U.S.C. § 103 as being unpatentable over Sudo in view of Meyer.

Claims 19 through 23 and 28 through 30 stand rejected under 35 U.S.C. § 103 as being unpatentable over Sudo in view of Onohara.

The full text of the examiner's rejections and response to the argument presented by appellants appears in the answer (Paper No. 23), while the complete statement of appellants' argument can be found in the main and reply briefs (Paper Nos. 22 and 24).

OPINION

In reaching our conclusion on the issues raised in this appeal, this panel of the board has carefully considered

appellants' specification[1] and claims, the applied teachings,[2] the affidavit of Dr. Michael W. Spallek and technical articles (Exhibit B), the affidavit of Dr. Ewald Spingler,[3] and the

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[1] We are informed by the "Description of the Prior Art" section of appellants' specification (pages 1 through 4) that, prior to the present invention, prefilled, sterile, disposable syringes for medicinal purposes were known. According to appellants (specification, page 2), in all known disposable syringes for injections of < 5 ml, the barrel of the syringe at the very least is made of glass. It is also pointed out (specification, page 3) that many types of glass are not suitable for gamma ray sterilization which is indicated to be a very simple, economical and harmless sterilization procedure. The specification (page 3) additionally indicates that prefilled, disposable plastic syringes with total fill volumes of at least 50 ml are known. As stated by appellants (specification, page 4), known prefilled plastic syringes could not be stored for long periods of time due to loss of preparation components due to diffusion. The specification (page 4) also notes that known plastic syringes are constructed from a translucent plastic, permitting only limited visual inspection of the syringe contents.

[2] In our evaluation of the applied teachings, we have considered all of the disclosure of each teaching for what it would have fairly taught one of ordinary skill in the art. See In re Boe, 355 F.2d 961, 965, 148 USPQ 507, 510 (CCPA 1966). Additionally, this panel of the Board has taken into account not only the specific teachings, but also the inferences which one skilled in the art would reasonably have been expected to draw from the disclosure. See In re Preda, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968).

[3] While labeled affidavits, the last paragraph of each of the Spallek and Spingler documents respectively reveals that they are declarations.

respective viewpoints[4] of appellants and the examiner. As a consequence of our review, we make the determination which follows.

We cannot sustain any of the examiner's rejections of appellants' claims for the reasons addressed below. Our focus, infra, will be upon the content of independent claims 13 and 24.

Each of independent claims 13 and 24 is drawn to a prefillable, low-particle, sterile, single use syringe for the injection of preparations having a filling volume of less than 5 ml with the syringe comprising, inter alia, a syringe body formed of plastic, with a filling volume within a syringe

[4] On pages 9 and 19 of the main brief (Paper No. 22), appellants refer to claimed wall thickness of 500 Fm as a separate feature. In light of the argument presented, it is not clear whether appellants view claim 13 as requiring a syringe cylinder wall thickness of 500 Fm. Based upon our reading of claim 13 and the underlying specification (page 12), it appears to us that the wall thickness of claim 13 is simply part of the standard for the measurement of desired water vapor permeability, i.e., less than 0.08 g/m^2 x d) relative to a wall thickness of 500 Fm. This matter should be resolved during any further prosecution before the examiner.

cylinder (portion) of less than 5 ml, and a protective cap of soft material covering an injection needle so that the needle pierces the protective cap and is thereby sealed.

The rejection of appellants' claims under 35 U.S.C. § 102(b)[5] is not well founded. As acknowledged by the examiner (answer, page 3), a filling volume of less than 5 ml is not set forth in Sudo. Further, it is apparent to us that such a filling volume is not inherent in the Sudo teaching. Additionally, the Sudo document fails to address a protective cap of soft material covering an injection needle so that the needle pierces the protective cap and is thereby sealed. Since the Sudo reference fails to disclose, either expressly or under principles of inherency, each and every element of

[5] Anticipation under 35 U.S.C. § 102(b) is established only when a single prior art reference discloses, either expressly or under principles of inherency, each and every element of a claimed invention. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997); In re Paulsen, 30 F.3d 1475, 1478-79, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994); In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990); and RCA Corp. v. Applied Digital Data Sys., Inc., 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984).

appellants' claimed invention, the anticipation rejection is not sound and must be reversed.

As to the respective rejections of appellants' claims under 35 U.S.C. § 103, we likewise conclude that they are not sustainable. Independent claims 13 and 24 stand rejected based upon the Sudo teaching alone. Consistent with our earlier stated views, we do not perceive that the Sudo teaching alone would have suggested the syringe of claims 13 and 24. Simply as an example of the deficiency of Sudo alone relative to the content of the independent claims, we do not discern any suggestion in this reference for a protective cap of soft material covering an injection needle so that the needle pierces the protective cap and is thereby sealed. The respective teachings of Cloyd, Meyer, and Onohara do not overcome the deficiency of the Sudo teaching as it pertains to the subject matter of independent claims 13 and 24.

REMAND TO THE EXAMINER

We remand this application to the examiner to consider

the following matters.

As evident from our assessment of the applied art above, there is no prior art teaching of the claimed feature of a protective cap of soft material covering an injection needle so that the needle pierces the protective cap and is thereby sealed. Should the examiner be aware of such a teaching, the examiner may determine it appropriate to reassess the patentability of the claimed subject matter. Starting with the knowledge in the art of glass syringes with filling volumes of less than 5 ml, a determination should be made as to whether the disclosures of Sudo and Kimber (U.S. Patent No. 5,135,514, of record) would have been suggestive of replacing glass with a cyclic olefin compound or polypropylene, respectively.[6] While glass may have been known to be used with prefilled, disposable syringes for injections of less than 5 ml (specification, pages 2 through 4), it does not appear that either of Declarants Spallek or Spingler were

[6] Appellants make reference to preferred cyclic olefin copolymers and glass-clear polypropylene (specification, pages 9 and 15).

aware of other knowledge in the art prior to appellants' invention, i.e., the teaching of Sudo (cyclic resin syringe wherein medicament liquid can be maintained in high quality) and Kimber (prefilled syringe barrel of polypropylene). Of course, other known prior art should also be considered as regards other features of the claims.

In summary, this panel of the Board has not sustained any of the examiner's rejections of appellants' claims. Additionally, we have remanded the application to the examiner to consider the matter discussed above.

The decision of the examiner is reversed.

REVERSED AND REMANDED

IRWIN CHARLES COHEN Administrative Patent Judge	)
CHARLES E. FRANKFORT	) BOARD OF PATENT

Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
	)	
JEFFREY V. NASE	)	
Administrative Patent Judge	)	

ICC:lmb

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MICHAEL D. BEDNAREK
KILPATRICK & CODY
700-13TH STREET, N.W., SUITE 800
WASHINGTON, DC 20005